

Stem Cell Center

The Stem Cell Center (SCC) supports stem cell focused process development, manufacturing, preclinical safety testing, and other activities needed to successfully apply to the FDA for approval to start a clinical trial. The SCC includes the Translating Center, which supports activities related to cell process development, manufacturing and research necessary to obtain an Investigational New Drug (IND) application – a prerequisite for clinical testing of cell therapy product candidates and the Accelerating Center which supports IND submissions and clinical trials for projects. Both CIRM-funded centers were awarded to IQVIA in 2016, creating the SCC.

The IQVIA SCC offers end-to-end pre-clinical, consulting, clinical development and commercialization services. Additionally, the SCC draws upon the expertise and operational excellence of world class organizations such as Charles River Laboratories and City of Hope for pre-clinical research and CMC services, respectively. The SCC offers services in the areas of:

- Pre-IND and IND-enabling preclinical/nonclinical services pharmacology and toxicology studies, process development, manufacturing
- IND-filing and clinical start-up services regulatory documentation, IND development and filing services, protocol development, IB generation
- Clinical conduct services clinical operations, safety monitoring, site selection and patient recruitment
- Commercial services health economics and outcomes research studies, real-world evidence strategy, pricing and market access assessments
- Project management services project management support
 to coordinate efforts across project stakeholders, ensure
 project stays on track and meet its milestones. For more
 information about CIRM project manager requirements, refer
 to this PDF.





For a more detailed overview of Stem Cell Center services, please refer to the following document:

• Stem Cell Center Core Services (2017) (PDF)

Contacting the SCC

To inquire about SCC services, please contact:

- Email: StemCellCenter@iqvia.com
- Phone: +1 (844) 399-5698

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• Address: 10188 Telesis Court Suite 400, San Diego, CA 92121

*If you are contacting the SCC regarding <u>CIRM translational awards or applications</u> and would like CIRM input on eligibility, please include **translational@cirm.ca.gov** with your correspondence to the SCC.

If you are contacting the SCC regarding <u>CIRM clinical awards or applications</u> and would like CIRM input, please include **clinical@cirm.ca.gov.

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